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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,993	12/28/2001	Susan McConnell	G&C 130.39-US-01	1833
22462	7590	05/24/2007		
GATES & COOPER LLP HOWARD HUGHES CENTER 6701 CENTER DRIVE WEST, SUITE 1050 LOS ANGELES, CA 90045			EXAMINER KOHARSKI, CHRISTOPHER	
			ART UNIT 3763	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/033,993	Applicant(s) MCCONNELL ET AL.	
	Examiner Christopher D. Koharski	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,9-25,27,30-37,39,43-59,62,64-68 and 107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,9-25,27,30-37,39,43-59,62,64-68 and 107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/19/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 3/19/2007 in which an RCE was filed with the addition of new claim 107. Currently claims 1, 2, 4, 5, 9-25, 27, 30-37, 39, 43-59, 62, 64-68 and 107 are pending for examination in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 13, 14, 17, 18, 19, 20, 22, 23, 24, 25, 27, 30-37, 39, 47, 48, 51-54, 56-59, 62, and 65-68 are rejected under 35 U.S.C 102(b) as being anticipated by Dugmore (WO 00/56384). Dugmore discloses an adjustable needle assembly device.

Regarding claims 1, 2, 4, 5, 13, 14, 17, 18, 19, 20, 22, 23, 24, 25, 27, 30-37, 39, 47, 48, 51-54, 56-59, 62, and 65-68, Dugmore discloses a flexible conduit housing (Figures 2A-C) and a base with a spool cartridge (Figures 9-11) that holds the flexible conduit and has a cover attached to the base (26) with an end (56) that is adapted to engage an infusion device (64).

Additionally, Dugmore discloses a device that is capable of infusing insulin into the body through the flexible conduit (12) via reservoir (74) (Figure 2A) to treat diabetes, wherein the flexible element can be dispensed to a certain length (Figures 2A-2C). Dugmore discloses a spool (Figures 3A-3C) that can dispense the conduit to fixed

length via the directional knob (80). The knob is driven under a ratchet and friction system (Figure 10, 11) that allows for retention at a fixed length.

Claim Rejections - 35 USC § 102

Claims 1, 24, 35, 58 and 107 is rejected under 35 U.S.C. 102(b) as being anticipated by Novosel (5,975,120). Novosel discloses an automatically retractable gas tubing feed spool.

Regarding claims 1, 24, 35, 58 and 107, Novosel discloses an apparatus used to deliver a fluid (see figure 1) including a flexible conduit (5) having an end adapted to connect to an infusion device and deliver a fluid from the infusion device through the flexible conduit to an individual having a physiological condition (col 2, ln 35-60), a base for temporarily housing the flexible conduit (14) having an opening for receiving the flexible conduit, a cover (18) attached to the base for substantially closing the opening, a spool (12) for receiving the flexible conduit, an interface adapted to attach the apparatus to a user so that the apparatus is carried by the user by an attachment tape means (16) (see abstract), wherein the conduit can be dispensed to a fixed variable length (Figures 1-2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-11, 15, 43-45, and 49 are rejected under 35 U.S.C 103(a) as being unpatentable over Dugmore in view of Peterson (US2003/0098067). Dugmore meets the claim limitations as described above except the center spool cartridge being replaceable.

However, Peterson teaches a gas-tubing reel.

Regarding claims 9-11, 15, 43-45 and 49, Peterson teaches a tubing reel that teaches a replaceable/removable spool (Figures 2-3, [0001]).

At the time of the invention, it would have been obvious use the replaceable/removable spool of Peterson with the system of Dugmore because it allows the housing to be reusable and allows for the ability to sterilize the different parts more effectively. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Peterson.

Additionally, It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the spool of Dugmore replaceable to make the housing reusable and allows for the ability to sterilize the different parts more effectively,

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since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Newin v. Erlichman*, 168 USPQ 177 (BdPatApp&Int 1969).

Claim Rejections - 35 USC § 103

Claims 12, 16, 21, 46, 50, 55 and 64 are rejected under 35 U.S.C 103(a) as being unpatentable over Dugmore in view of Novosel (5,975,120). Dugmore meets the claim limitations as described above except the tubing being dispensed from each end of the conduit housing with a clamshell shape.

However, Novosel teaches and automatically retractable gas tubing feed spool.

Regarding claims 12, 16, 46, 50 and 64, Novosel teaches a tubing reel that comprises a reel with a tubing hub that allows for the tubing to be withdrawn from both ends to extend and retract the tubing into the clamshell shaped housing (Figures 1-2).

At the time of the invention, it would have been obvious to add the tubing hub of Novosel to the system of Dugmore to incorporate the extension of the medical conduit from both ends to allow for connection to devices that span different distances. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Novosel.

Response to Arguments

Applicant's arguments with respect to claim 107 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 3/19/2007 have been fully considered but they are not persuasive. In response to applicant's argument regarding the Dugmore reference (see above rejection), Applicant's representative asserts that the end of Dugmore is not adapted to connect to an infusion device due in part to the disclosure of the needle end being able to be removed from a matrix and being an unsafe needle hazard.

Examiner disagrees; the needle end (54) shown in the Dugmore reference (WO 00/56384) is capable of being connected to an infusion device and is capable of transmitting fluids (Dugmore discloses the transmittal of fluids through the needle (54) to tube (66)). By design the needle end can pierce the tube of an infusion device or a rubber septum connected to an infusion device. Additionally, Examiner also asserts that as stated in the rejection above the Novosel (5,975,120) reference discloses ends (5,7) of a flexible conduit that are capable of being connected to an infusion device, the structure is similar to Applicant's and no discernable structure is present in the claims to establish differently; also Applicant's own drawings disclose a similar flexible tubing end structure (see Applicant's Figure 1B). Therefore Examiner asserts where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function, see *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed

apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

Suggested Allowable Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests the addition of specific structure added to claim 107 including specific structure drawn to the flexible tubing end adapted to be connected, element 204 (Figure 2), or element (114) (Figure 1B) drawn to the gripping winding surface of the device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

5/19/07



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